

REMARKS

Claims 1-17 and 35 are pending following the election of Group I for prosecution. Claims 18-33 and 36 are canceled herein. Claim 34 was previously canceled. Support for the amendments to the claims may be found throughout the specification, for example on page 3, lines 31-32. Support for the amendments to the specification may be found in Claim 18 and 34 as originally filed. No new matter has been added as a result of these amendments.

1. Foreign Priority

Applicants note that they are currently undertaking the necessary steps to comply with the requirement under 35 U.S.C. 119(b) to submit a certified copy of the priority document.

2. Election/Restrictions

Applicants herewith confirm their election, without traverse, to prosecute the invention of Group I, *i.e.* Claims 1-17 and 35.

3. Claim Rejections – 35 U.S.C. §112, first paragraph

The Office Action has rejected claims 1, 3, 4, 7-17, and 35 under 35 U.S.C. §112, first paragraph, under the assertion that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Office Action asserts that the specification only discloses that the determination of triglyceride level in lipoprotein is suitable for low-density lipoprotein (LDL) triglyceride, not the genus including other lipoprotein class triglycerides. Applicants respectfully traverse this assertion.

Applicants note that the written description requirement for a claimed genus “may be satisfied through sufficient description of a representative number of species by actual reduction to practice... or by disclosure of the relevant, identifying characteristics ... sufficient to show the applicant was in possession of the claimed genus.” (Emphasis added). MPEP 2163(II)(A)(3)(a)(ii). Applicants contend that the instant application, in combination with the knowledge already possessed by one of skill in the art, does in fact disclose such relevant, identifying characteristics.

The specification discloses a method for determining the triglyceride level in LDL. However, contrary to the assertion of the Office Action, the specification further discloses a method of determining triglyceride level in lipoproteins other than LDL. The Office Action, in making its assertions, points to page 3, which the Office interprets as “clearly indicat[ing] that this method is limited to LDL determination.” Applicants respectfully contend that the Office has misinterpreted the teachings of the specification. The disclosed methods are not limited to the determination of the triglyceride content of the LDL class of lipoproteins, but rather to the selective determination of the triglyceride content of a single class of lipoproteins in a given sample. As the specification indicates (see page 3, final paragraph), the present invention provides for *selective* solubilization of specific lipoprotein fractions. As such, the triglyceride content of, for example, LDL can be selectively determined, or, if the selectivity is so adjusted, the triglyceride content of, for example, HDL can be selectively determined. As further noted in the specification, (page 3, line 38), the composition of the POP/POE block copolymer can be adjusted to selectively solubilize a particular lipoprotein class.

Additionally, the specification, in the first paragraph of page 4, discloses that one of skill in the art could manipulate the block copolymer in order to selectively solubilize a specific lipoprotein. Specifically, the specification discloses that the block units, as well as their ratio, may be manipulated to achieve the desired selectivity, and that influencing parameters include the degree of polymerization, the polymerization length, etc. Furthermore, on page 5, the specification discloses that the selectivity with regard to a particular lipoprotein class can be increased through the use of agents for aggregation. Thus one of skill in the art would clearly recognize the relevant, identifying characteristics of the claimed genus.

Based on the arguments above, Applicants respectfully request reconsideration and withdraw of the rejection of claims 1, 3, 4, 1-17, and 35 under 35 U.S.C. §112, first paragraph, for lack of written description.

4. Claim Rejections – 35 U.S.C. §112, second paragraph

The Office action has rejected claims 1-17, and 35 under 35 U.S.C. §112, second paragraph, under the assertion that they are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the

Office Action asserts that Claim 1, part (a) is unclear and indefinite for the recitation of “reaction” because it is uncertain as to the type of reaction being utilized, chemical or electrical.

In response, Applicants have amended Claim 1, part (a) to recite “selective solubilization.” Support for this amendment may be found throughout the specification, for example on page 3, lines 31-32. Applicants contend that as amended, the pending claims are definite and therefore respectfully request reconsideration and withdraw of their rejection under U.S.C. §112, second paragraph.

5. Claim Rejections – 35 U.S.C. §103

The Office Action has rejected Claims 1-17 and 35 under 35 U.S.C. §103(a) under the assertion that they are unpatentable over Shirakawa in view of Wieland et al., Pandya et al., and Schmolka. Applicants respectfully traverse this assertion.

In order to establish a *prima facie* case of obviousness the combination of prior art references must teach or suggest all of the claim elements. Presently pending Claim 1, on which all of the claims ultimately depend, is drawn a procedure for the determination of triglyceride contained in lipoprotein having the following measures: a) selective solubilization of triglyceride-containing lipoprotein with a non-ionic surface-active agent, which is synthesized from a block copolymer of propylene oxide and ethylene oxide, and b) carrying-out of a triglyceride determination method.

Shirakawa teaches a method of measuring “a living body component” in a reagent containing a cyclodextrin and a nonionic surfactant. As the Office has acknowledged, Shirakawa does not disclose the determination of triglyceride contained in lipoprotein. More significantly, Shirakawa does not teach the selective solubilization of triglyceride-containing lipoprotein. Furthermore, as the Office has acknowledged, Shirakawa does not teach a non-ionic surface-active agent which is synthesized from a block copolymer of propylene oxide and ethylene oxide.

Wieland et al. does nothing to cure this deficiency. Wieland teaches the determination of triglycerides in lipoproteins that have been separated by gel electrophoresis. Wieland does not teach the selective solubilization of triglyceride-containing lipoprotein with a non-ionic surface-active agent, which is synthesized from a block copolymer of propylene oxide and ethylene oxide.

Likewise Pandya does not cure the deficiency of Shirakawa, or of the combination of Shirakawa and Wieland. Pandya merely teaches that the physical properties of a POP/POE block copolymer, one type of nonionic surfactant, may be varied with temperature. Pandya is silent on the use of POP/POE copolymers to solubilize biological polymers. Specifically, Pandya neither teaches nor suggests the selective solubilization of triglyceride-containing lipoprotein with a non-ionic surface-active agent.

Similarly, Schmolka does not cure the deficiency of Shirakawa, or of the combination of Shirakawa, Wieland, and Pandya. Schmolka merely reviews the physical properties and applications of various block copolymer surfactants. Pandya neither teaches nor suggests the selective solubilization of triglyceride-containing lipoprotein with a non-ionic surface-active agent.

Furthermore, in order to establish a *prima facie* case of obviousness, there must be some suggestion or motivation, within the prior art references themselves, to combine the references. “The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.” MPEP 2143.01, *citing In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

Applicants first note that Wieland in fact teaches away from the presently claimed invention. As noted in the instant application, on page 2, lines 16-26, Wieland teaches the electrophoretic separation of lipoproteins, a method in which the fractionation steps are both labor and time intensive. Contrary to the assertion of the Office Action, there would be no motivation to combine the electrophoretic method of Wieland with the “living body component” solubilizing method of Shirakawa.

Furthermore, contrary to the assertion of the Office Action, there would be no motivation to combine the tri-block copolymer of Pandya with Shirakawa. As noted above, Pandya merely teaches that the physical properties of a POP/POE block copolymer are a function of temperature, and is silent on the use of POP/POE copolymers to solubilize biological polymers. As such, there would be no motivation to combine the teachings of Pandya with those of Shirakawa.

Thus as there is no motivation to combine the cited references, and the cited references, either alone or in combination, do not teach or suggest all of the claim limitations, a *prime facie* case of obviousness cannot be established.

For the forgoing reasons, Applicants contend that that the rejections of the pending claims based on 35 U.S.C. §103 have been overcome and respectfully request that these grounds of rejection be withdrawn.

CONCLUSIONS

Applicants respectfully contend that all conditions of patentability are met in the pending claims as amended and therefore respectfully request allowance.

If the Examiner believes it to be helpful, the Examiner is invited to contact the undersigned representative by telephone at (312) 913-0001.

Respectfully submitted,
McDonnell Boehnen Hulbert & Berghoff LLP

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